Neurim under fire again? – The Advocate General's opinion in the Santen referral (C-673/18)

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Today, Advocate General (AG) Mr. Giovanni Pitruzzella handed down his opinion in the referral C-673/18 (*Santen*). The case concerns an SPC based on a second medical use/formulation patent and stems from a referral to the CJEU made by the Paris Court of Appeal with decision of 9 October 2018 in *Santen v. INPI* (see here for an English translation of the referral decision), which was previously reported on this blog.
As a refresher, in the landmark decision *Neurim* (C-130/11) of 19 July 2012 the CJEU ruled that SPCs may also be granted for a "different application" of a previously approved drug, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the SPC application.

The *Neurim* decision is highly controversial, as it is in conflict with the literal wording of the provisions of the SPC Regulation, as well as the previous standing case law, as evidenced by *Pharmacia* (C-31/03), *Yissum* (C-202/05) and *MIT* (C-431/04).

The concept of a "different application" within the meaning of *Neurim* has thus given rise to considerable uncertainty and further referrals. Already in the *Abraxis* (C-443/17) case, AG Mr. Henrik Saugmandsgaard Øe had pointed out that the SPC Regulation is *de facto* incompatible with the position adopted by the CJEU in *Neurim*, and had advised the court to depart from this standpoint altogether, or at most restrict it to situations where the first approval is for a veterinary product, and the subsequent approval, forming basis of the SPC application, is for a medicinal product for human use.

As discussed previously on this blog, the CJEU in *Abraxis* (C-443/17) has chosen not to address the conflict in the case law highlighted by the Advocate General. Nevertheless, the CJEU in *Abraxis* endorsed a narrow interpretation of *Neurim*, ruling that a new formulation of an old drug may not form basis of an SPC, thereby addressing one of the central questions raised by the Paris Court of Appeal in *Santen*.

The guidance sought by the referring French court in *Santen*, however, goes very much beyond the issues raised in *Abraxis*. Yet, the nature of the remaining questions raised in *Santen* would appear to reflect the cautious position advocated by the referring court in relation to *Neurim*. Thus, the Paris Court of Appeal phrased suggestive questions in terms of the implications of the concept of a "different application" within the meaning of the *Neurim* decision, asking in particular:

- whether the concept of a "different application" relied upon in *Neurim* is to be limited solely to the case of a human application that follows a prior veterinary application;
- or whether it only concerns an indication relating to a new therapeutic field, in the sense of a new medical specialty, compared to the earlier marketing authorization, or a medicinal product in which the active ingredient exerts an action different from that which it exerts in the medicinal product that was the subject of the first marketing authorization;
- or whether, more generally, with regard to the objectives of the SPC Regulation aimed at putting in place a balanced system that takes into account all the interests at stake, including those of public health, it is to be assessed under stricter criteria than those applying to the assessment of patentability of inventions.

In his opinion issued today, AG Pitruzzella provides a remarkably thorough and elaborate analysis of the *Neurim* judgment and its ramifications in the context of the legal framework of the SPC Regulation as well as the corresponding case law of CJEU, which makes this opinion more than worth reading.

As to *Neurim*, AG Pitruzzella highlights that the CJEU's reasoning in this decision goes well beyond the specific factual circumstances of the underlying case and introduces a significant new interpretation of the concept of the "product" in the SPC Regulation. This, according to AG Pitruzzella, prohibits any attempt to understand *Neurim* as a specific exception to an otherwise strict interpretation of the concept of the "product", as doing so would betray both the spirit and the letter of *Neurim*.

Notably, the Advocate General not only points out the blatant contradictions between *Neurim* and the CJEU's earlier decisions in *Pharmacia* (C-31/03), *Yissum* (C-202/05) and *MIT* (C-431/04) but also the inextricable inconsistency between *Neurim* and the CJEU' very recent judgment in *Abraxis* (C-443/17). Even if *Neurim* were (inappropriately) interpreted as a narrow exception, this would still not resolve its incompatibility with *Abraxis*.

Against this backdrop, AG Pitruzzella calls on the CJEU to make a clear choice and either bluntly reject the *Neurim* approach or embrace it wholeheartedly and adopt a broad interpretation of the concept of the "product".

To the disappointment of research-based pharmaceutical industry, the principal suggestion of the Advocate General is that the CJEU should completely abandon the *Neurim* approach and return to a strict literal interpretation of the Article 3(d) requirement, such that SPCs would no longer be available for any new therapeutic applications of previously approved active ingredients. AG Pitruzzella thereby endorses the same suggestion that was already made by AG Saugmandsgaard Øe in his opinion in the earlier *Abraxis* referral.

Only as an auxiliary suggestion, for the case that the CJEU should wish to hold on to *Neurim*, AG Pitruzzella suggests that the CJEU should endorse a balanced interpretation of *Neurim* which is in between the extremes proposed by the referring French court. In particular, there is nothing in the CJEU's reasoning in *Neurim* that justifies a restriction of the scope of application of the *Neurim* approach to the specific (and rare) situation where a prior veterinary approval is followed by a later approval of the same active ingredient for human medicinal use.

According to the Advocate General, *Neurim* should rather be understood as covering two distinct cases of application: first, the case of a ***new therapeutic application***, i.e. the case where the invention protected by the basic patent allows the treatment of a new disease, and second, the case that the active ingredient in question exerts a ***new pharmacological, immunological or metabolic activity*** which is different from the previously known activity (which formed the basis of the prior approval of that same active ingredient).

In relation to the above-mentioned first case, the Advocate General further expounds, in footnote 98 of his opinion, that a new therapeutic application can also be made possible by a new formulation of an old active ingredient, and that the *Neurim* approach should likewise be applicable to such cases (which are different from the situation in *Abraxis* where the new formulation was not approved for a new therapeutic application).

The Advocate General then turns to the second question raised in the referral from the Paris Court of Appeal, which relates to the notion of a therapeutic application "within the limits of the protection conferred by the basic patent" relied upon in the *Neurim* decision; specifically, the French referring court asked whether this notion means that the scope of the basic patent should have to be limited to the new therapeutic indication which is specified in the marketing authorization relied upon for the SPC filing. This suggestion is plainly rejected by AG Pitruzzella who finds nothing in the *Neurim* decision that would support such an understanding.

Instead, the Advocate General cuts right to the chase and emphasizes that the protection conferred by such an SPC, as provided in Article 4 of the SPC Regulation, can only extend to the corresponding new therapeutic application but must not cover the product as such or any other therapeutic applications of this product (even if they fall within the scope of protection of the basic patent). Therefore, in full accordance with *Neurim*, Article 4 has to be interpreted as meaning that the "product" of such an SPC, which is directed to a new therapeutic application of a previously approved active ingredient, is not the active ingredient as such, but rather the new application of that active ingredient.

Altogether, the suggested approach of applying *Neurim* that has been outlined by AG Pitruzzella (albeit only as a secondary option) appears remarkably balanced and well thought through. If adopted by the CJEU, it would finally put the widely acclaimed *Neurim* judgment that was rendered almost a decade ago on solid legal footing and would cement the availability of SPCs for new therapeutic applications of previously approved drugs.

As always, it remains to be seen whether and to what extent the CJEU will follow the Advocate General's suggestions. While the CJEU's forthcoming decision in the *Santen* referral is expected to largely clarify the availability of "second medical use SPCs" in general, it should not be left unmentioned that there is a further pending referral, *Novartis* (C-354/19), which addresses the closely related question of whether the grant of a new SPC for a different therapeutic application is precluded if the new SPC is filed by the same rights holder who has already been granted an SPC for the same active ingredient before, on the basis of a patent protecting the active ingredient as such. It would thus seem that the precise conditions under which SPCs may be available for new therapeutic applications are finally set to be resolved.

Dr. Alexa von Uexküll *and* ***Oswin Ridderbusch****, both partners at the IP-specialized law firm Vossius & Partner, are the editors of the handbook* ***European SPCs Unravelled: A Practitioner's Guide to Supplementary Protection Certificates in Europe*** *published by Wolters Kluwer in 2018. See here for a review by Judge Jürgen Schell (in German) and a review by Miquel Montañá (in English).*